

# CAPSULIT<sup>®</sup>

S.p.A.

Since  
1949



**Corporate brochure**



L-carnitine 2000 mg  
LOT: 01373  
EXP: 04/2023

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# About

**Capsulit is a company leader manufacturer of safety closures for the pharmaceutical industry.**

Founded in 1949, with more than 70 years of history dedicated to the Pharma sector, Capsulit confirms an important experience fundamental to guarantee integrity, quality and product safety. Besides our origin as manufacturer of capping machines, enables us to have better specific knowledges and competences on the closing systems. The agile structure and the double production technology consisting of aluminium and plastic, make Capsulit a reactive and flexible company very much appreciated by customers for its service and expertise.

**Capsulit Giglioli is a company specialized in the production of PET bottles, vials and jars for the nutraceutical and pharmaceutical industry.**

Founded in 1989, the company "GIGLIOLI FABRIZIO", has developed and specialized its activity in the primary packaging, and in particular in the processing of plastics and in the production of PET vials and bottles for the pharmaceutical, nutraceutical, food and cosmetic industries. Over the years, the company has always distinguished itself for its customer orientation and for the quality of the products made, characteristics much appreciated by Capsulit, which in 2019 incorporated, attributing it the new company name "CAPSULIT GIGLIOLI".

**Capsulit Iberica is a distribution company in the Iberian market.**

Founded in 1974, Capsulit Iberica company specializes its activity in the distribution of packaging for the pharmaceutical and food sectors for the Iberian market. With a warehouse of 6,500 square meters, the Spanish company is appreciated for its efficient service, rapid delivery and the ability to maintain stock for its customers to whom it guarantees Just in Time deliveries.



# Why choosing Capsulit

## FOR ITS EXPERIENCE

Operating in the pharmaceutical sector for over 70 years, Capsulit can now rely on a stable collaboration with over 500 customers, consisting of multinational pharmaceutical groups, medium-sized companies, up to small pharmaceutical laboratories.

## FOR ITS FLEXIBILITY

In terms of range of offered products. In terms of service, thanks to its agile medium-sized company structure that allows rapid management of deliveries and services according to customer requests.

## FOR ITS QUALITY

Product quality: Capsulit supplies products of high quality consistency, which guarantee excellent machine runnability, and high functional performances thanks to the sophisticated vision systems installed on most of its production lines.

Quality system: Capsulit has developed a certified quality system, strongly based on GMP standards.

## FOR ITS PARTNERSHIP

Capsulit has developed a wide range of products on specific customer request, thanks to the support of its internal R&D center and consolidated experience made available at the customer's service.



# Production



Thanks to a double production technology of aluminium and plastic and to automated assembling systems Capsulit produces a wide range of products entirely made within the company. Production is managed according to the “Industry 4.0” logic. All machines are interconnected to the company information system, which allows continuous monitoring of production and automatic progress of orders. All the products are completely traceable thanks to warehouse with radio-frequency system and barcode.

## “CAPSULIT” PRODUCTION DEPARTMENTS

### Aluminium processing departments

- Production of caps from aluminium coils
- Production of caps from aluminium sheets

### Plastic processing departments

- Production of measuring cups and dosing spoons by injection
- Production of bottles by IBM (Injection Blow Molding)

### Assembling

- For top cap for injectable
- For child proof caps for syrups and antibiotics
- For droppers
- For caps with various inserts, as pourer, dropper, syringe adapter and dehydrating insert with silicagel

## “CAPSULIT GIGLIOLI” PRODUCTION DEPARTMENTS

### Plastic processing departments

- PET bottles and vials by injection stretch blow molding
- HDPE and PP by injection blow molding
- Bottles by extrusion blow blowing
- Closures, medical devices and plastic articles by injection molding

### Assembling department

- Assembling of medical devices

### Silk screening department

- Silk screening for vials and bottles

**All Capsulit Giglioli productions take place in ISO8 certified clean rooms**

# Products



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## Tethered Caps

Closures are also available in tethered version: tamper evident caps for single-dose, tamper evident caps for pilfer proof mouths, tamper evident and child resistant caps for pilfer proof mouths, caps for extemporaneous use. Tethered caps, created in compliance with the **European Directive 2019/904**, remain attached to the bottle, even after opening, thus avoiding dispersion into the environment.

Different versions and colors of the cap have been created to suit all customer needs and the different types of bottles and vials that Capsulit produces.



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## Screw Plastic Caps

### Plastic Tamper Evident Pilfer Proof (PP) and Child Proof (CP) Caps

- Suitable for pilfer proof mouth according to UNI 6144
- Available in the most used diameters
- Available in PP or HDPE
- Very precise screw thread
- Available with a wide variety of liners that ensures compatibility with each product both in liquid and solid form
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks
- Child proof function certified ISO 8317 and FDA
- Available in Tethered version according to EU Directive SUP 2019/904
- Available in plastics derived from biological instead of fossil origins

### Dessicant Insert

The caps can be supplied with pre-assembled plastic insert containing silicagel Caps are assembled and filled with silicagel internally in a specific department.

### Adaptor for dosing pipettes

The caps can be supplied with pre-assembled adaptor suitable for glass or plastic bottles neck. Available for different type of syringes or pipettes.

### Plastic Caps for Pill Jars

- Suitable for jars neck 38 mm diameter
- Available in tamper evident version and in No-tamper evident version
- Available in PP or in HDPE material
- Available with a wide variety of liners that ensures compatibility with each product both in liquid and solid form
- Available with induction liner, pressure sensitive liner, Lift'n peel liner
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks
- Available in plastics derived from biological instead of fossil origins



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## Aluminium caps

### Pilfer Proof Caps (UT)

- Suitable for pilfer proof mouth according to UNI 6144
- Available in all standard diameters (from 17 mm up to 38 mm)
- Printable with customizable writings, logos and colours
- Available with a wide variety of liners that ensures compatibility with each product both in liquid and solid form
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks
- Available in Child Proof version with a plastic Cover Cap certified ISO 8317

### Dessicant Insert

The caps can be supplied with pre-assembled plastic insert containing silicagel.

Caps are assembled and filled with silicagel internally in a specific department.

### Other inserts

Available also some other type of insert as the adaptor for syringes, droppers, pourers, and conical inserts.





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## Caps for injectables

### PS – Aluminum Caps

- Centre tear off caps in aluminium according to ISO norms
- Available in diameters 13, 20, 29, 32 mm
- Available in several colours
- Easy tear-off opening lever completely closed available for diameter 29 mm (LE version)

### Top Cap – Plastic and Aluminum Caps

- Centre tear off caps with aluminum skirt and plastic top according to ISO and DIN norms
- Available in diameters 13, 20, 28, 32 mm
- Tamper evident thanks to different hooking systems: plastic wings (TC version) or aluminum bridges (FO version)
- Available in standard colours and on demand
- Customizable with logos and brand names both on the top or on the skirt
- Available in different heights
- Available in different plastic disc shapes (flat, bordered, aligned to the skirt) and finishings (matt and shiny)

### Extra Services

- Ready to be sterilized: special packing as Tyvek bags, heat-sealed PE bags, according to the different sterilization processes
- Ready to use: gamma ray treated and beta ray treated, processes validated according to ISO 11137 norm
- Bioburden test or sterilization test on a representative batch sampling



## Plastic Measuring Cups



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- CE marked according to MDR 2017-745
- Produced according to ISO 13485 norm
- Silkscreened or engraved dosing levels according to customers' needs
- Available in different plastic materials
- Matching with a wide range of plastic and aluminium closures
- New models realization on customer's request
- Available in plastics derived from biological instead of fossil origins



## Dosing Spoons



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- CE marked according to MDR 2017-745
- Produced according to ISO 13485 norm
- Engraved dosing levels according to customers' needs
- Available in different shapes
- In line automatically piled up, tied and packed with robots
- Available in different plastic materials
- New models realization on customer's request
- Available in plastics derived from biological instead of fossil origins



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## Caps for single dosage oral liquid

### Facila (SC)

- Fully tear off cap for DIN mouth aluminum made and manufactured with the “easy open” technology according to ISO and DIN norms
- Printable with customizable writings, logos and colours
- Available with a wide variety of liners that ensures compatibility with each product both in liquid and solid form
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks

### Top Facila (TF)

- Fully tear off cap for DIN mouth with aluminum skirt manufactured with the “easy open” technology and plastic top according to ISO and DIN norms
- Available in standard colours and on demand
- Customizable with logos and brand names both on the top or on the skirt
- Available in different heights
- Available in different plastic disc shapes (flat, bordered, aligned to the skirt) and finishings (matt and shiny)
- Available with a wide variety of liners that ensures compatibility with each product both in liquid and solid form

- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks

### Facila plast (FP)

- Pressure tamper evident plastic made cap for 20 mm DIN mouth
- Fully removable with lateral tab
- Available in different colours
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks
- Available in plastics derived from biological instead of fossil origins

### Screw Caps

- Tamper evident plastic made cap for screw mouth
- Suitable for vial neck 14 mm and 18 mm diameter
- Available in different colour
- Available in Tethered version according to EU Directive SUP 2019/904
- Available in plastics derived from biological instead of fossil origins
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks



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## Biphase Kit

### Closing system for DIN mouth 20 mm

- Closing system for extemporary solutions to be mixed at the moment of use
- Pressure tamper evident plastic made cap
- PE breakable base container for the active principle
- PP Plunger
- Available with capacity 0,5 ml
- Available in different colours
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks
- Available in plastics derived from biological instead of fossil origins

### Closing system for screw mouth 18 mm

- Closing system for extemporary solutions to be mixed at the moment of use
- Screw tamper evident plastic made cap
- PE breakable base container for the active principle
- PP Plunger
- Available with capacity 0,5 – 0,8 – 1 ml
- Completely removable kit by unscrewing the cap
- Available in different colours
- Conformity to European and US food contact laws, conformity to European and US pharmacopeia, absence of hazardous substances and BSE, TSE risks
- Available in plastics derived from biological instead of fossil origins
- Available in Tethered version according to EU Directive SUP 2019/904



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## Bottles

- Manufactured with IBM technology (Injection Blow Molding) and injection, stretch and blow molding technology
- Produced in PET, HDPE, PP, LDPE, R-PET and PLA
- Available in different colours
- New models on customer's request
- Calibrated mouth and dimensional precision
- Constant and controlled weight
- Available in plastics derived from biological instead of fossil origins

### **Screw single dose bottles & vials**

- Produced in PET, R-PET and PLA
- Available with 14 and 18 mm diameter mouth and in different sizes from 7 to 25 ml
- Custom silkscreen printing available as an extra service

### **DIN single dose bottles & vials**

- Produced in PET, R-PET and PLA
- Available with 14 and 20 mm diameter mouth and in different sizes from 7 to 25 ml
- Custom silkscreen printing available as an extra service

### **Multi dose bottles**

- Produced in PET, R-PET, HDPE and PLA
- Available with 28 mm diameter pilfer proof mouth and in different formats from 60 ml to 500 ml
- Available also with other mouths and sizes

### **Pill Jars**

- Produced in PET, R-PET and PLA
- Available with 38 mm diameter screw mouth, in different sizes from 60 ml to 500 ml

# Research & Development

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Past experience of Capsulit in the construction of filling and closing machines for the pharmaceutical industry and his internal R&D has led to the creation of numerous patents. Capsulit designs its products independently and is able to design cutting moulds for aluminum and plastic and equipment for their assembling.

In collaboration with its customers, Capsulit is always available for the creation of specific products for their needs.



# Extra Services

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## Caps “ready to use”

- Production and gamma ray treatment process validated according to ISO 11137
- Production and beta ray treatment validated according to ISO 11137
- Special Packing in double or triple heat-sealed PE bag

## Caps “ready to be sterilized”

- Tyvek packaging for autoclave sterilization
- Special Packaging in double or triple heat-sealed PE bag
- Portbag packaging solutions

## Product customization

- Lithographed aluminium caps with logos and colors upon specific customer request
- Caps with customized plastic top with engraved or tampographed logos
- Silk screened single-dose bottles
- Medical devices (measuring cups and dosing spoons) with silk-screened or engraved level marks.

## Special Packaging

- Aluminium packaging for capsules with dehydrating insert
- Special packaging for stacking spoons
- Special packaging on trays for oriented packaging of bottles
- Customized packaging upon customer request



# Quality and Certifications

## Capsulit is certified:

- MDR 2017-745 MARCATURA CE
- ISO-9001-2015
- ISO 13485 – 2016
- ISO 15378-2017
- ISO 14001-2015
- ISO 45001-2018
- Ecovadis Silver Medal



## Capsulit operates in the full respect of GMP (Good Manufacture Practice) Norms

Following carefully all the rules, procedures and guidelines, object of ISO 15378 certification.

Always in the same context, every aspect of the production processes is documented in detail, thus ensuring a level of quality that meets the demanding requirements of the pharmaceutical industry.

The traceability is guaranteed and documentation and counter samples are kept for 6 years + 1 year (the current one) and for medical devices are kept for 10 years.

## The vision control systems guarantee quality and integrity of the product

In addition to the in-process controls, Capsulit production lines are equipped with automatic vision systems with cameras that help to prevent defects on each single produced cap; thanks to this sophisticated system all defective parts are automatically rejected out of the

line, thus ensuring total control over all manufactured products.

- On-line inspection of 100% of finished products
- Automatic rejection of defective pieces
- Color control
- Dimensional control
- Check integrity
- Control of aesthetic defects
- Checking wordings and trademarks
- Challenge test

## Quality Control

- Informatic Quality System
- Incoming Controls
- In Process and Final Controls
- Instruments directly connected to the PC



# Sustainability\*



## **UNI EN ISO 45001 Certification**

Employees Health and Safety.

Integrated approach for job organization, safety managing and health protection.

## **UNI EN ISO 14001 Certification**

Respect and Protection of the Environment.

Reduction of the emissions and waste, limitation of the noisy emissions, interventions aimed to the reduction of energetic consumption.

## **Code of Ethics**

Application of principles concerning the respect of laws and of moral values towards all subjects.

## **Ecovadis Silver Medal**

Company commitment to reducing environmental impact, continuous improvement of working conditions, attention to its employees and the relationship with suppliers, customers and communities and maintenance of company management inspired by good practices and ethical principles.



### **Sustainability Report**

Performance and impacts across a wide range of sustainability topics: environmental, social and governance.

### **Social Responsibility**

Local initiatives as gardening care, disabled services, periodical invitations to school students, sponsorships of youth sports, construction of cycle paths and parkings in the municipality in which it is located.

### **Initiatives for the Environment**

- Production of electricity from renewable sources (current photovoltaic plant of 629 kWp + 264 kWp to be realized on the new building)
- Insulation interventions of all the buildings for energy saving
- Progressive replacement of hydraulic presses with high energy saving electric presses
- Progressive replacement of compressors with high energy efficiency compressors and periodic search for air leaks in the compressed air system
- Closed circuit press cooling system for water saving and equipped with air convectors which in the summer allow the presses to be cooled without the use of refrigerators and in the winter to cool the presses and molds
- Items in polypropylene and polyethylene produced with material obtained from sugar cane or other biological sources, bottles produced from food contact compliant R-PET recycled material according to the percentage requested by the customer, bottles produced with materials of biological origin and compostable
- Use of cardboard boxes and pallets only FSC certified (the cellulose and wood used come only from responsibly managed forests)
- Separate waste collection and separation of aluminium, polypropylene, polyethylene, polystyrene waste, all reused as secondary raw materials from the point of view of the circular economy



*\*Sustainability Report and Code of Ethics are available on our website: [www.capsulit.it](http://www.capsulit.it)*



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